

Parkland Memorial Hospital
5201 Harry Hines Boulevard
Dallas, Texas 75235
214 590 8000

6954 '99 SEP 30 A3:12

September 22, 1999



Parkland

The Director
Center for Biologics Evaluations and Research (CBER)
Food and Drugs Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockfield, Maryland 20852

Re: Change in the FDA's policy for Current Good Manufacturing Practice for Blood and Blood Components:
Supplemental Testing and the Notification of Consignees and Transfusion Recipients of Donor Test Results for Antibody to HCV

Dear Sir/Madam:

As members of the Blood Utilization Review Committee of Parkland Memorial Hospital, we wish to express our concern regarding the decision under consideration that "look back" for hepatitis C be extended back for an indefinite period or as long as records are readily retrievable. We are concerned that the high rate of false positive tests with the early EIA 1.0 method, combined with the time consuming record retrieval, would make "look-back" difficult, would cause unnecessary anxiety in those notified, and be unlikely to provide clinically useful information. Our experience with "look-back" for recipients of blood from donors subsequently positive to the later EIA 2.0 and 3.0 HCV antibody methods, did not uncover a single case of HCV that was previously unknown.

We feel the resources of our hospital and Transfusion Service could be much better utilized than in this type of historic "look back" process. We have far more concerning issues in Transfusion Medicine at present, in particular related to blood shortages and the need for recruitment to replace the donors excluded by the increasingly stringent restrictions mandated by the FDA for Creutzfeldt-Jakob disease and other conditions.

Yours sincerely,

Cynthia Rutherford, M.D.
Chairman, Blood Utilization Review Committee
Parkland Memorial Hospital.

99D-1878

C 28

*Parkland Memorial Hospital
5201 Harry Hines Boulevard
Dallas, Texas 75235*

CERTIFIED

Z 196 262 905

MAIL

REGISTERED
FIRST CLASS



U.S. POSTAGE

02.98

METER 432805

**RETURN RECEIPT
REQUESTED**

The Director
Center for Biologics Evaluations Research
Food and Drug Administration
Dockets Management Branch (HFA-305)
5630 Fishers Lane, Room 1061
Rockfield MD 20852



Parkland

20857X0001

